Title: **Quality Control Record Sheet**
3 Screen ICA ELISA Kit QC Data

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Page 1 of 1

Prepared by: G Flood
Approved by: F Ryrie

Kit lot number: KZGIE72C Kit expiry date: 26th November 2024

Reagent Lot Numbers:

3 Screen Coated Wells:	ZGIE41	Expiry date:	11 Dec 2024
3 Screen-Biotin:	ZGIB27c	Expiry date:	26 Nov 2024
Recon. Buffer for 3 Screen-Biotin:	3BB25	Expiry date:	13 Mar 2025
Streptavidin Peroxidase:	GEP567	Expiry date:	25 Dec 2024
Diluent for SA-POD:	PB175	Expiry date:	30 May 2025
Peroxidase Substrate:	PTS183P	Expiry date:	24 Oct 2026
Stop Solution:	HESP125	Expiry date:	31 May 2025
Concentrated Wash Solution:	CW343	Expiry date:	05 Jul 2025
Reference Preparation:	ZGIR42	Expiry date:	17 Jan 2025
Calibrators:	ZGIC42	Expiry date:	17 Jan 2025
Negative Control:	ZGIN42	Expiry date:	17 Jan 2025
GAD Ab Positive Control:	3SGP42	Expiry date:	17 Jan 2025
IA-2 Ab Positive Control:	3SIP42	Expiry date:	17 Jan 2025
ZnT8 Ab Positive Control:	3SZP42	Expiry date:	17 Jan 2025

Curve and Controls: Incubation temp: 21 °C

	Absorbance at 450 nm	Absorbance at 405 nm
Calibrator 5 units per mL	0.071	0.022
Calibrator 15 units per mL	0.134	0.042
Calibrator 100 units per mL	0.510	0.162
Calibrator 400 units per mL	2.125	0.676
Calibrator 2000 units per mL	>4	2.209
Reference Preparation	0.530	0.167
Negative Control	0.032	0.009
GAD Ab Positive Control	1.011	0.320
IA-2 Ab Positive Control	0.489	0.155
ZnT8 Ab Positive Control	0.283	0.090

Control	Concentration at 450 nm (units per mL)	Concentration at 405 nm (units per mL)	Range (units per mL)	Index Value at 450 nm	Index Value at 405 nm	Range (index value)
Negative	<5	<5	<5	<30	<30	<30
GAD Ab Positive	199.4	192.2	200±80	190.8	191.6	200±80
IA-2 Ab Positive	95.6	96.0	100±40	92.3	92.8	100±40
ZnT8 Ab Positive	52.4	55.5	53±21	53.4	53.9	56±22

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay performed by: Fiona Ryrie
Signature: Fiona Ryrie
Position: Scientist
Date: 27th October 2023

Authorised by: DR G Flood
Signature:
Position: HEAD OF QC
Date: 24TH NOV 2023